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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,519	09/17/2001	Mitchell Keegan	50179-088	9129

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EXAMINER

WILSON, MICHAEL C

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 02/25/2003

2

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,519

Applicant(s)

KEEGAN ET AL.

Examiner

Michael C. Wilson

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-3 and 6-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The preliminary amendment filed 4-16-01, paper number 8, has not been entered because the request to amend claims 4, 7-9, 13, 14, 16-18, 24, 26 and 27 is not in the proper format. A clean copy and a marked up copy of the amendments should be provided. The amendment filed 9-17-01, paper number 5, has been entered. The amendment filed 1-27-03, paper number 10, has been entered. Claims 4 and 5 have been canceled. Claim 28 has been added. Claims 1-3 and 6-28 are pending and under consideration in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-3 and 6-13, drawn to an expression cassette encoding an insulin secretory signal operably linked to a sequence encoding somatotropin, cells having such an expression cassette, and a method of making somatotropin using such cells.

Group II, claims 14, 15 and 17-28, drawn to a capsule for implantation comprising cells comprising an expression cassette encoding an insulin secretory signal operably linked to a sequence encoding somatotropin, and a method of administering somatotropin to a host using such a capsule.

Group III, claims 16 and 18-20, drawn to a method of administering somatotropin to a host comprising administering an expression cassette encoding an insulin secretory signal operably linked to a sequence encoding somatotropin.

Art Unit: 1632

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The "special technical feature" of the invention is an expression cassette encoding an insulin secretory signal operably linked to a sequence encoding somatotropin. However, the special technical feature is not a contribution over the prior art. The special technical feature lacks an inventive step over Cullen (1988, DNA, Vol. 7, No. 9, pg 645-650) taken with O'Mahony (1989, Animal Genetics, Vol. 20, 313-316). Cullen taught expression vectors encoding an insulin secretory signal operatively linked to a heterologous protein enhanced protein expression. Cullen did not teach the protein was somatotropin. However, O'Mahony taught the cDNA sequence of porcine somatotropin. Thus, it would have been obvious to the skilled artisan at the time of filing to replace the heterologous protein taught by Cullen with somatotropin as taught by O'Mahony to increase expression of somatotropin *in vitro*.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1632

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is 703-305-0120. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



MICHAEL WILSON
PRIMARY EXAMINER